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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
ZHOU, SHUBO

ART UNIT	PAPER NUMBER
1631	

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DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,966	NATHAN, ASHER	
	Examiner	Art Unit	
	Shubo "Joe" Zhou	1631	

SAM

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) 2 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☒ Claim(s) 1 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/20/01, 3/21/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election

Applicants' election of Group I (claim 1) in the response filed 11/28/03, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 1-2 are currently pending, and claim 1 is under examination.

Claim 2 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the communication filed 11/28/03.

The Abstract filed 3/22/02 is acknowledged. However, it was inadvertently damaged. A copy of the Abstract is requested.

Priority

It is noted that this application appears to claim subject matter disclosed in prior provisional application 60/206,959 and a series of other provisional applications as shown on pages 1-2 of the specification. However, the specification only states that "this application is related to the following United States Provisional patent applications ...". If applicants indeed intend to claim the benefits of the provisional applications, references to these applications should be made clearly indicating "this application claims the benefit of ...", as recommended by the M.P.E.P. 201.11, III B.

Information Disclosure Statement

The Information Disclosure Statements filed on 9/20/01 and 3/21/02 have been entered and considered. Initialed copies of the form PTO-1449 are enclosed with this action.

Specification

The disclosure is objected to because of the following informalities:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claim is directed. The title is directed to drug-amino acids chimeric molecules whereas the elected invention is a method for improving the pharmacological activity of a drug.

The specification is not page-numbered.

In the first paragraph of the second page of the specification, multiple blanks are present. Further, the phrase "co-pending US patent applications filed on even date herewith" in the same paragraph is confusing.

The question mark in the citation of a reference "(Grimm, C., Lund, t., and Dahlberg, J.E. 1997. Proc. Natl. Acad. Sci. USA 94:10122-10127., Grimm, C., Lund, E., and Dahlberg, J.E. 1997. EMBO J. 16:(4):793-?)" in the last paragraph of the eighth page of the specification needs to be replaced by the appropriate number.

The period "." in the phrase "system described above.that are administered to a biological system" on the 15th page of the specification needs to be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no clear connection between step f) and g)-j). Step g) creates a subsequent population of expressed amino acid sequences, but the claim does not require that the amino acid sequences are expressed from the nucleic acids generated from step f).

The metes and bounds of the term " a drug" in step h) and step j) are not clear. It is unclear whether this is the same drug as the drug recited in step b), or it can be any other drug.

Step j) appears to comprise two sub-steps, the "identifying" step and the "combining" step. However, the period between the words "target" and "and" is confusing. Further, the phrase "the amino acid sequence of the final population" (note the singular form) in step j) lacks clear antecedent basis. The final population in step i) comprises multiple "expressed amino acid sequences" (note the plural form). Thus, it is unclear which single sequence of the final population of sequences is required in the sub-step "combining" of step j). Furthermore, the

claim does not end with a period as if more steps were required. If this were true, it is unclear what other steps are required.

The preamble of the claim recites "a method for improving the pharmacological activity of a drug", but the claimed method ends with a step of "combining the amino acid sequence of the final population with a drug". It is not clear how the pharmacological activity of a drug is improved.

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Toole et al. (IDS document: WO 92/14843, September 3, 1992) in view of Brodin et al. (IDS document: WO 98/34110, August 6, 1998).

Toole et al. disclose a method of identifying nucleic acids that complex to a target molecule. The method comprises creating a population of mixtures of nucleic acids and combining the mixture with cells of a cell line, and isolating the target by isolating the nucleic acids. See pages 23, 30. The cell line is considered as a biological system as required in the instant claim. The method steps are repeated and the nucleic acid amplified to enrich the nucleic acid bound to a target. See page 38-39. The isolated nucleic acid bound to a target can itself be used as a therapeutic drug, or it can be linked to auxiliary substances such as a drug to enhance or complement its function. See the paragraph bridging pages 16 and 17.

However, Toole et al. do not explicitly teach that amino acid sequences are linked to a drug and form a drug-amino acid-target complex. Brodin et al. teach a method of identifying an antibody that complexes with a target. The method comprises mixing a population of amino acid sequences of an library of antibody or a combinatorial library with a target in a biological system such as tissue sections or cultured cells using a phage display system. See pages 7, 10, 15. The nucleic acids for the isolated amino acids that bind to a target are amplified (page 4), and the isolated amino acids are enriched by multi-round selections. Brodin et al. point out that the method is an application of a highly efficient method for the direct selection of a binding structure as an antibody phage towards displayed target structures expressed in vivo and represented by antigens in situ. See page 18. And the method provides an extension of the application of phage technology for the selection of antibodies to complex antigens, thus making

it generally applicable to identify antibodies directed against a number of important and/or novel target antigens and epitopes, and facilitates identification and dissection of antigens which are exclusively expressed in vivo.

One of ordinary skill in the art would be motivated by Brodin et al. to modify the method of Toole et al. to use amino acid sequence to bind to targets take advantage of the phage display system which enables the finding of therapeutic antibodies against in vivo targets, many of which are proteins, and the identification of protein targets which are exclusively expressed in vivo. There would have been a reasonable expectation of success because Toole et al. and Brodin et al. provide the detailed experimental procedures.

Claim Objections

Claim 1 is objected to because of the following informalities:

The claim does not end with a period and there is a period in step j) between the words "target" and "and".

Appropriate correction is required.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael

Woodward, Ph.D., can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst William Phillips whose telephone number is 571-272-0548, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shubo (Joe) Zhou, Ph.D.

Patent Examiner

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER